

**Appl. No.** : 10/647,131  
**Filed** : August 22, 2003

### **REMARKS**

Claims 1-18 were previously pending. Claims 1 and 6 have been amended. New claims 19-25 have been added by this amendment. Support for each of these amendments can be found in the claims as originally filed and throughout the specification. No new matter has been added to this application.

Support for the amendment to claim 1 can be found throughout the specification. Support for the term "orally admisterable" can be found, for example, at paragraph 29, lines 1-4. Support for the terms "tablet" and "capsule" can be found, for example, in paragraph 30, lines 1-7 and paragraph 50.

Support for the term "prevention" in amended claim 6 can be found, for example, at paragraph 12, line 1.

New claims 19-25 have been added. The newly added claims are fully supported by the specification and claims as originally filed. In particular, support for claim 19 can be found, for example, at paragraph 30, lines 7-8 and at paragraph 50, lines 5-6. Support for claim 20 can be found, for example, at paragraph 35. Support for claim 21 can be found, for example, at paragraph 22, lines 4-9. Support for claim 22 can be found, for example, at paragraph 37. Support for claim 23 can be found, for example, at paragraphs 35 and 37. Support for claim 24 can be found, for example, at paragraph 34. Support for the term "pharmaceutical excipient" in claim 25 can be found, for example, in the specification at paragraph 30, lines 1-7.

#### Regarding the Restriction Requirement

Applicants provisionally elected Group 1, claims 1-5, with traverse, by telephone conference with the Examiner on July 7, 2005. With respect to the election of species, Applicants elect "nattokinase" as the species of fibrinolytic agent, and "pine bark extract" as the species of antioxidant. All of the claims read on the elected species.

Applicants note, however, that Claim 1 is generic. Accordingly, upon allowability of the claims with respect to nattokinase and pine bark extract, Applicants are entitled to seek consideration of the nonelected species as provided in 37 C.F.R. § 1.141.

Further, Applicants respectfully traverse the requirement for restriction for the following reasons. Claims 6-18 are drawn to a method of decreasing or preventing swelling of the lower extremities, edema, pulmonary embolism, or thrombosis, by administering the pharmaceutical

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preparation of claim 1. In the event that the currently pending composition claims are found to be patentable, it would not require any further searching to determine the patentability of the currently pending method claims. Thus, there is no undue burden to the Examiner for searching the method claims 6-25. Accordingly, in an event that the currently pending composition claims are found patentable, Applicants respectfully request the rejoinder of Groups I and II for prosecution in the instant application.

Discussion of Rejection Under 35 U.S.C. § 103(a)

The Examiner rejects claims 1-5 under 35 U.S.C. § 103(a) as being unpatentable over Akatsuka, JP 06311849, WO002076240, JP2002360220, or JP20022291436, taken with Milstein, Ganan-Calvo, Norris, or JP2003095964.

The Examiner alleges that Akatsuka, JP 06311849, WO002076240, JP2002360220, and JP20022291436 each teach that natto kinase is known to be added to foods; and further that Milstein, Ganan-Calvo, Norris, and JP2003095964 each teach that pine bark is known to be added to foods.

The Examiner alleges that it would be obvious for one of skill in the art to add the pine bark and the natto kinase to form one single composition since they were both individually known in the art to be used for the same purpose, namely to be used in foods.

The invention recited in the pending claims would not be obvious to one with ordinary skill in the art. The invention of Claim 1 has now been amended to add "wherein said pharmaceutical preparation is in the form of an orally admisterable tablet or capsule." None of the cited documents, either alone or in combination, teaches or suggests a pharmaceutical preparation comprising effective amounts of a fibrinolytic agent and an antioxidant, wherein said pharmaceutical preparation is in the form of an orally administerable tablet or capsule. The only compositions taught by any of the references are food compositions.

None of the cited references, either alone or in combination, contains all of the elements of claim 1, as now amended. None of the cited references describe or suggest a tablet or capsule comprising a fibrinolytic agent, such as nattokinase, or an antioxidant, such as pine bark extract. Even if after reviewing the above-cited references, one of skill in the art were motivated to combine a fibrinolytic agent and an antioxidant in food preparations, there would be no

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motivation to combine these agents to form a tablet or capsule. Accordingly, Applicants respectfully request that the rejection of claims 1-5, under 35 U.S.C. § 103(a) be withdrawn.

#### CONCLUSION

Applicants believe that all outstanding issues in this case have been resolved and that the present claims are in condition for allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to contact the undersigned at the telephone number provided below in order to expedite the resolution of such issues.

No fees are believed due at this time; however, if fees are deemed necessary, please apply any credits or charges, including any fee for an extension of time, to Deposit Account No. 11 1410.

Respectfully submitted,

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